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Comparison of the paper-based and electronic versions of the Dermatology Life Quality Index: evidence of equivalence

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Conflicts of interest
A.Y.F. is joint copyright owner of the Dermatology Life Quality Index for which Cardiff University (grant no: 509937) and A.Y.F. receive royalties.

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Summary

Background The use of patient-reported outcome measures in electronic format has been increasing. However, these formats are usually not validated or compared with the original paper-based formats, so there is no evidence that they are completed in the same way.

Objectives To compare the conventional paper version with a web-based application (iPad®) version of the Dermatology Life Quality Index (DLQI) to assess equivalence of scores.

Methods The study employed a randomized crossover design using a within-subjects comparison of the two formats of the questionnaire. International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines were followed. Participants aged over 18 years with any confirmed skin condition were recruited from a teaching hospital dermatology outpatient clinic. Expected intraclass correlation coefficient (ICC) was 0·9 ($\alpha = 0{\cdot}05$).

Results A total of 104 patients were recruited, median age 53·5 years (interquartile range 37·3–67·8; 43% male). The ICC showed high concordance between the total DLQI scores from paper and iPad versions (ICC 0·98; 95% confidence interval 0·97–0·99). Patients took a median of 78 s to complete the electronic version and 73 s for paper ($P = 0{\cdot}008$): 76% preferred the electronic version and perceived completion to take a shorter time.

Conclusions There is high concordance and thus equivalence between the iPad and paper versions of the DLQI, with an ICC of 0·98, and a clear patient preference for the iPad version.

What's already known about this topic?

- The use of patient-reported outcome measures (PROs) in electronic format has been increasing.
- Electronic formats are usually not validated or compared with their original paper-based formats, but are assumed without evidence to be comparable.
- The benefits of using electronic PROs include portability, real-time monitoring of patients' quality of life and improved data capture.

What does this study add?

- There is equivalence between completing the Dermatology Life Quality Index (DLQI) on paper and in an electronic format.
- Patients prefer the electronic format to the paper version although the electronic format takes slightly longer to complete.
- This equivalence testing of the electronic format of the DLQI with the paper version will reassure and encourage such use in clinical and research settings.

What are the clinical implications of this work?

- The DLQI application (app) will increase routine assessment of quality of life with negligible addition to consultation time.
- The DLQI app may facilitate transfer of patient data to electronic records, potentially being incorporated into referral systems from primary care.
- It is hoped the results of this study will encourage validation of other patient-reported outcome measures in electronic format in dermatology and other medical specialties.

There is increasing interest in utilizing technology within clinical medicine: innovations include computerized data entry,[1,2] communication initiatives[3] and virtual reality.[4] Within dermatology, there have been several innovations using electronics and information technology.[5–7] The use of patient-reported outcome measures (PROs) in electronic format has also been increasing.[8] However, these formats are usually not validated or compared with their original paper-based versions. This may result in data that are incomparable between the two formats due to the lack of equivalence.[9] Coons *et al.*[10] have proposed guidelines detailing the level of evidence required to demonstrate equivalence, depending on the amount of modification to the original PRO.

The Dermatology Life Quality Index (DLQI)[11] is the most commonly used dermatology-specific quality of life (QoL) measure in clinical trials.[12–14] The DLQI is easy to use in clinical practice due to its brevity and simplicity[15] with an average completion time of 2 min.[16] In the current era of widespread use of digital devices such as tablets and smartphones, clinicians, researchers and patients often use nonvalidated electronic versions instead of the original paper version. However, there is an underlying concern over whether such data are comparable with two decades of data gathered via the validated paper DLQI,[11,14] posing several challenges in data analysis and interpretation. The availability of a DLQI application (app) that had been validated would alleviate such concerns and contribute to better management of patients with skin conditions by having an easy tool for regular monitoring of disease severity from the patient's own perspective. Moreover, this tool could potentially be used by general practitioners to decide which patients need to be referred, as well as provide reassurance for users of electronic QoL measures across dermatology and other medical fields.

This study aimed to compare the conventional paper-based with a novel web-based app version of the DLQI, following International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines,[10] with respect to patient acceptability and preference and in terms of consistency of scores. We also assessed whether there was a carryover effect depending on which format patients completed first (paper vs. iPad®).

Participants and methods

Study participants

The study employed a randomized crossover design using a within-subjects comparison of the two formats of the questionnaire. The study was conducted at the dermatology outpatient department, University Hospital of Wales, Cardiff, U.K. Inclusion criteria were patients aged 18 years or older with any confirmed skin condition, and the ability to read and understand English. The exclusion criteria were patients who were not able to read and/or understand written English; having a coexisting medical or second dermatological condition of considerable severity as determined by the investigator; or physical deformities that would prevent writing or use of an iPad. The study protocol was approved by a local ethics committee (ref. 14/SW/0085, South West – Central Bristol Research Ethics Committee, U.K.) and the Cardiff & Vale University Health Board Research and Development department. Written informed consent was given by each subject prior to entering the study.

The Dermatology Life Quality Index iPad® application

The DLQI consists of 10 questions concerning a dermatology patient's perception of the impact of their skin disease on

different aspects of their QoL over the last week. The items of the DLQI include symptoms and feelings, daily activities, leisure, work or school, personal relationships and the side-effects of treatment. Each item is scored on a 4-point scale: not at all/not relevant, a little, a lot, and very much. Scores of individual items (0–3) are added to yield a total score (0–30); higher scores indicate greater impairment of QoL. The DLQI has been shown to be a strong instrument with respect to its internal consistency, reproducibility, validity and sensitivity to change.[14,15,17–19]

The DLQI was developed into an electronic app on the iPad by Janssen EMEA in conjunction with the original copyright holder (A.Y.F., Cardiff University). Only this particular iOS version was tested for the purpose of studying equivalence. The individual items and their response categories/scale were unchanged, allowing users to select options using touch. The app (Psoriasis 360©) is available without charge and may be downloaded from the Apple App Store (https://appsto.re/gb/-JIFw.i). It is also available from the Google (Android) App Store (https://play.google.com/store/apps/details?id=com.sapnagroup.p360&hl=en_GB). The DLQI paper version and a screenshot of the iPad app version are shown in Figure 1a and b, respectively.

Study procedure

Eligible patients were asked to complete the DLQI, both paper and electronic versions. The order of completing the questionnaires (paper version first vs. iPad version first) was randomized using a random number generator. After 30 min, patients were asked to complete the other format (Fig. 2). A 30-min interval was used to minimize patient waiting time and

(a)

DERMATOLOGY LIFE QUALITY INDEX

DLQI

Hospital No: Date:
Name: Score:
Address: Diagnosis:

The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST WEEK. Please tick one box for each question.

1.	Over the last week, how **itchy**, **sore**, **painful** or **stinging** has your skin been?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	
2.	Over the last week, how **embarrassed** or **self conscious** have you been because of your skin?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	
3.	Over the last week, how much has your skin interfered with you going **shopping** or looking after your **home** or **garden**?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	Not relevant ❒
4.	Over the last week, how much has your skin influenced the **clothes** you wear?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	Not relevant ❒
5.	Over the last week, how much has your skin affected any **social** or **leisure** activities?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	Not relevant ❒
6.	Over the last week, how much has your skin made it difficult for you to do any **sport**?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	Not relevant ❒
7.	Over the last week, has your skin prevented you from **working** or **studying**?	Yes No	❒ ❒	Not relevant ❒
	If "No", over the last week how much has your skin been a problem at **work** or **studying**?	A lot A little Not at all	❒ ❒ ❒	
8.	Over the last week, how much has your skin created problems with your **partner** or any of your **close friends** or **relatives**?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	Not relevant ❒
9.	Over the last week, how much has your skin caused any **sexual difficulties**?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	Not relevant ❒
10.	Over the last week, how much of a problem has the **treatment** for your skin been, for example by making your home messy, or by taking up time?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	Not relevant ❒

Please check you have answered EVERY question. Thank you.

Fig 1. (a) The original Dermatology Life Quality Index (DLQI) questionnaire.[11] (b) Example screenshot from the DLQI iPad® app. The DLQI is copyright © A Y Finlay, G K Khan, April 1992. This must not be copied without the permission of the DLQI authors.

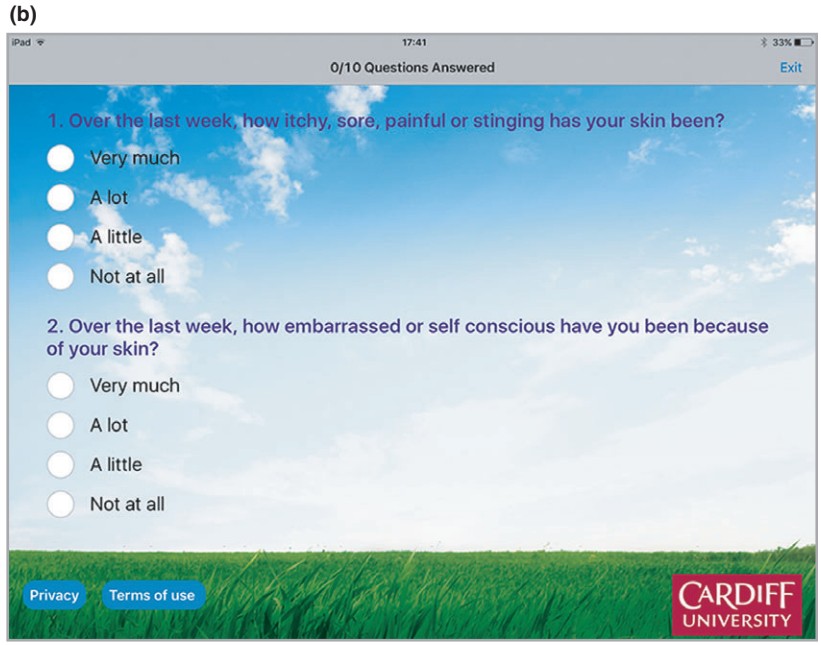

Fig 1. Continued

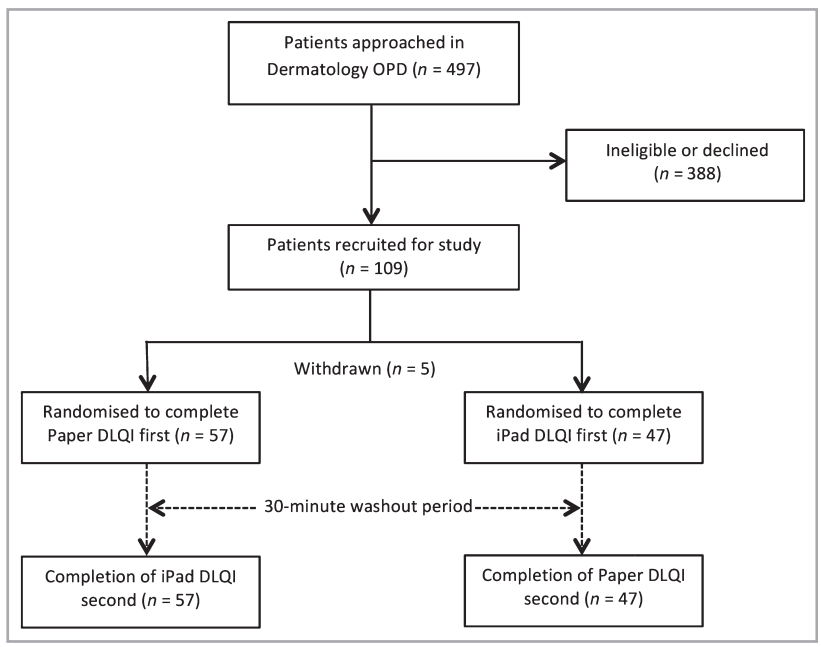

Fig 2. Flow diagram of the study procedure. OPD, outpatients department; DLQI, Dermatology Life Quality Index.

burden, as following up patients to complete the study at a later date would result in a higher cost and increase the chances of change in disease severity.[10] In between testing, the research team ensured that patients read a magazine, talked to staff or used their phones to browse, as forms of distraction.

Training to operate the app was given in person to every subject by a member of the research team, who remained with the patient throughout the duration of completion in case the subject needed assistance. The app also has basic instructions on the home screen and all patients were given time to read this prior to completion. Prior to completing either format of the DLQI, patients also completed a short demographic questionnaire on age, gender, literacy levels, visual and tactile impairments, diagnosis, and previous use of tablet computers or the DLQI. Completion of both versions was conducted in a similar environment; both completions by the participant were either before or after meeting the doctor, in order to reduce the effect of the doctor's consultation upon patient-reported QoL. The time taken to complete the DLQI using the paper version and the app was recorded. Patients were asked to also complete a short questionnaire asking about their perception, attitude and experience with the paper-based and web-based methods, concerning ease or difficulty of administration, acceptability, time requirement, feasibility and being comfortable with disclosing personal information using the novel app-based method.

Sample size

Sample size was calculated in accordance with ISPOR guidelines.[10] The study power was set at 95%, with an expected intraclass correlation coefficient (ICC) of 0·9 ($\alpha = 0{\cdot}05$), resulting in a target sample size of 104 patients.

Data analysis

Data analysis was conducted using SPSS version 20 (IBM, Armonk, NY, U.S.A.). Concordance of DLQI scores between paper- and app-based data was analysed using a two-way fixed-effects ICC model, which is the most commonly utilized statistical measure in equivalence studies of this nature.[20] The Wilcoxon signed-rank test was used to compare DLQI scores and completion times between the two formats; both variables were shown by the Shapiro–Wilk test to be non-normally distributed. A more stringent score difference of 1 point (3%) between the two versions was considered equivalent, although the majority of studies target a maximum of 5% difference.[20] Subanalysis was conducted to identify any carryover effect depending on which format of the DLQI patients completed first. Bland–Altman plots were drawn to measure the limits of agreement between the two formats. Equivalence was considered with limits of agreement ≤4, which is the minimal clinically important difference (MCID) for the DLQI.[21]

Descriptive analysis was used to present demographic data of the patients and their feedback on the preference and experience of using the tools. Linear regression techniques were used to identify correlation of iPad completion times with age.

Results

Sociodemographic characteristics of the study participants

A total of 104 patients were recruited, mean age 52 years ± 18·7; 43% male. Demographic details are given in Table 1. The most common diagnoses were psoriasis (39%), 'skin lesion' (19%) and eczema (13%). The majority of patients (61%) had their highest level of education at school; 17% of patients had never used a tablet before and 46% stated that they were 'a little' or 'not' comfortable with a tablet prior to participating in this study.

Comparisons of validity and reliability

As shown in Table 2, the ICC shows high concordance between total DLQI scores from paper and iPad versions [ICC = 0·98; 95% confidence interval (CI) 0·97–0·99]. The median difference of scores was also within the hypothesized difference of ±1 point (P = 0·006) (Fig. 3). The lower and higher limits of agreement were −3·1 and 4·1, respectively (Fig. 4). Patients took a slightly longer time to complete the DLQI on the iPad than on paper. The median of the individual

Table 1 Demographic characteristics of the study participants

	All (n = 104)	Paper first (n = 57)	iPad® first (n = 47)
Age, years			
Mean ± SD	51·5 ± 18·7	51·5 ± 19·3	51·4 ± 18·2
Median (IQR)	53·5 (37·3–67·8)	54 (33–68)	50 (38–67)
Range	20–89	20–89	20–85
Sex			
Male	43·3 (45)	51 (29)	34 (16)
Female	56·7 (59)	49 (28)	66 (31)
Nationality			
British	91·3 (95)	91 (52)	92 (43)
Other	8·7 (9)	9 (5)	9 (4)
First language			
English	90·4 (94)	88 (50)	94 (44)
Welsh	1·9 (2)	4 (2)	–
Other	7·7 (8)	9 (5)	6 (3)
Education			
Secondary school	60·6 (63)	58 (33)	64 (30)
University	37·6 (41)	42 (24)	36 (17)
Visual impairment			
None	59·6 (62)	65 (37)	53 (25)
Glasses	29·8 (31)	25 (14)	36 (17)
Other condition	5·8 (6)	5 (3)	6 (3)
Unspecified	1·9 (2)	4 (2)	–
Missing data	2·9 (3)	2 (1)	4 (2)
Tactile impairment			
Yes	9·6 (10)	9 (5)	11 (5)
No	90·4 (94)	91 (52)	89 (42)
Diagnosis			
Unknown	2·9 (3)	5 (3)	–
Skin lesion	19·2 (20)	23 (13)	15 (7)
Psoriasis	38·5 (40)	33 (19)	45 (21)
Eczema/dermatitis	13·5 (14)	14 (8)	13 (6)
Alopecia	1·0 (1)	–	2 (1)
Vitiligo	1·9 (2)	2 (1)	2 (1)
Infection	3·8 (4)	4 (2)	4 (2)
Acne/folliculitis	6·7 (7)	5 (3)	9 (4)
Cyst	2·9 (3)	4 (2)	2 (1)
Cutaneous malignancies	1·9 (2)	2 (1)	2 (1)
Allergy	1·0 (1)	2 (1)	–
Hidradenitis	1·9 (2)	4 (2)	–
Autoimmune/ inflammatory condition	1·9 (2)	2 (1)	2 (1)
Missing data	2·9 (3)	2 (1)	–
Tablet use			
Daily	49·0 (51)	40 (23)	60 (28)
Less often	32·7 (34)	44 (25)	19 (9)
Never	17·3 (18)	14 (8)	21 (10)
Missing data	1·0 (1)	2 (1)	–
Tablet comfort			
Very comfortable	52·9 (55)	54 (31)	51 (24)
A little comfortable	30·8 (32)	30 (17)	32 (15)
Not comfortable	15·4 (16)	14 (8)	17 (8)
	1·0 (1)	2 (1)	–
Used DLQI before?			
Yes	9·6 (10)	7 (4)	12·8 (6)
No	89·4 (93)	93 (53)	85 (40
Missing data	1·0 (1)	–	2 (1)

All data are presented as % (n) unless otherwise stated. IQR, interquartile range; DLQI, Dermatology Life Quality Index.

Table 2 Equivalence analysis of paper and electronic Dermatology Life Quality Index (DLQI) overall median scores and median completion time

	Paper	iPad®	ICC (95% CI)[a]	Difference (P – I)	Limits of agreement[b]	
					Lower	Upper
DLQI scores (n = 104)						
Median (IQR)	5 (1–12)	4 (1–11)	0·98 (0·97–0·99)	0·0 (0–1)[c]	−3·1	4·1
DLQI times (min:s)						
Median (IQR)	1:13 (00:56–01:36)	1:18 (1:03–1:39)	0·59 (0·39–0·72)	−0:09 (00:25–00:13)[c]		

CI, confidence interval; ICC, intraclass correlation; IQR, interquartile range; P – I, paper score minus iPad score. [a]Hypothesizing coefficient of ≥0·9. [b]Limits of agreement calculated from Bland–Altman plots (Fig. 4). [c]P-value <0·05 calculated from Wilcoxon signed-rank test.

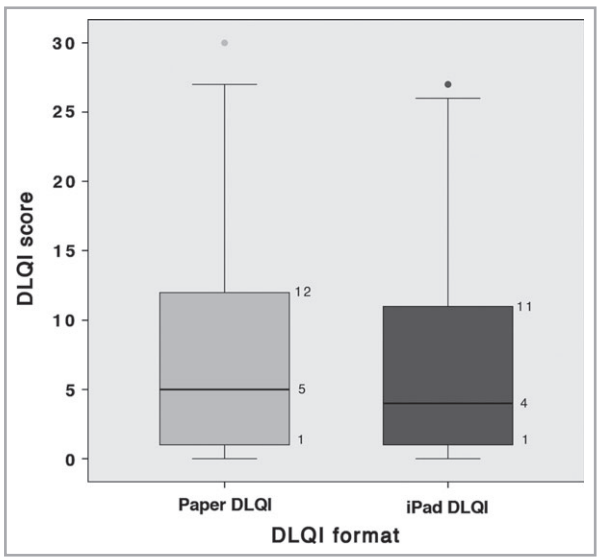

Fig 3. Box plot demonstrating the score distribution of both paper and iPad® Dermatology Life Quality Index (DLQI) formats. The bottom whisker represents the lowest value, and the upper whisker represents the highest value. The dot represents one outlier. The upper level of the box represents the 75th percentile and the lower level of the box represents the 25th percentile. The broad horizontal line in the middle of the box represents the median.

time differences was 9 s [interquartile range (IQR) −25–13; P = 0·008]. However, as shown in Table 3, there was no carryover effect on scores (P = 0·56) or completion times (P = 0·76) regardless of which format of the DLQI was used first. Linear regression demonstrated that the time taken to complete the iPad version was weakly correlated in a positive way with age, with older patients taking slightly longer (R^2 = 0·257; P = 0·012). The estimated increase was 8 s for each 10-year increase in age.

Comparisons of applicability and practicality

Patients were asked: 'On a scale of 1 to 10, where 1 is very uncomfortable and 10 is very comfortable, how comfortable were you using the iPad application version of the DLQI?'. In addition, patients were asked: 'On a scale of 1 to 10, where 1 is very difficult and 10 is very easy, how easy did you find it to use the iPad application version of the DLQI?'. Both questions were also asked about the paper version of the DLQI. Patients found both paper and iPad versions were easy (mean 9·4 ± 1·3 for paper and 9·6 ± 1·3 for iPad) and comfortable to use (mean 9·4 ± 1·1 for paper and 9·6 ± 1·4 for iPad) (Table 4). Overall, 57% of patients reported perceived time to complete the iPad version as shorter than that of the paper version. Which format was used first had an effect on the perceived time of iPad completion: more patients perceived a shorter time with iPad when paper was used first than when iPad was used first (70% vs. 43%; P = 0·023). The feedback results in other areas were the same whether paper or iPad was completed first. The majority of patients (76%) preferred the iPad version to paper. Patient demographics or previous experience with tablets did not have any effect on choice of preference and completion of the questionnaire.

Discussion

PROs in electronic formats are increasingly being used over their paper counterparts due to their inherent benefits, including a more streamlined process as well as increased reliability of data.[20] If not validated alongside the paper format, several new PROs are being validated initially in electronic format[22,23] to facilitate easier and higher quality data analysis and to reduce the overall cost of administration and storage. Paper-based instruments have a number of limitations such as higher rate of missing values; higher error rates in selecting multiple responses for single-option items; data entry error[24] in transferring responses from paper to electronic databases; and higher costs associated with administration, collection and processing the data.[25] These issues can be avoided by the use of computer-based administration (CBA) of QoL questionnaires.

However, CBA of PROs presents several challenges.[26,27] In routine clinical practice, assessment (at each visit) of disease severity and of QoL is labour intensive, requiring a major commitment of resources. Ease of use is one of the most important factors necessary for assessing QoL as part of routine clinical practice. Furthermore, patients may not be accustomed to such input devices or may be hindered by lack of internet connectivity.[8]

CBA of QoL measures such as in the form of web-based apps using touchscreen computers, also called tablets (e.g. iPad), is one of the ways that more frequent assessments can be conducted with minimal burden on patients and clinical

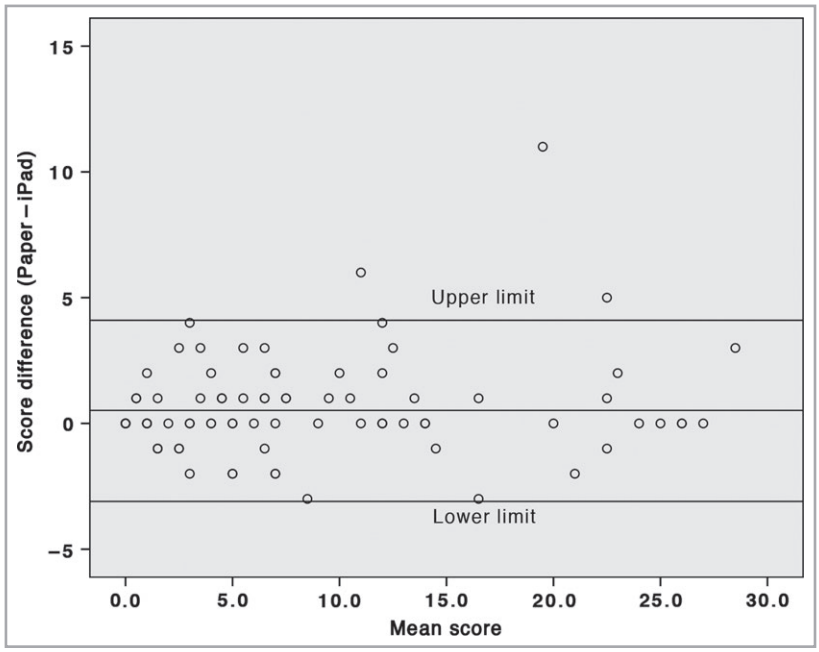

Fig 4. Bland–Altman plot demonstrating Paper and iPad® Dermatology Life Quality Index score agreement.

Table 3 Equivalence and carryover analysis of paper and electronic Dermatology Life Quality Index

	All (n = 104)	Paper first (n = 57)	iPad® first (n = 47)
Paper score			
Median (IQR)	5 (1–12)	5 (1–12·5)	6 (1–12)
Range	0–30	0–26	0–30
iPad score			
Median (IQR)	4 (1–11)	4 (0·5–10)	6 (1–12)
Range	0–27	0–26	0–30
Paper time (min:s)			
Median (IQR)	01:13 (00:56–01:36)	01:24 (01:06–01:40)	01:03 (00:50–01:29)
Range	00:28–04:15	00:28–04:15	00:30–02:49
iPad time (min:s)			
Median (IQR)	01:18 (01:03–01:39)	01:13 (00:58–01:27)	01:25 (01:09–01:53)
Range	00:35–08:24	00:35–08:24	00:49–02:49
Score difference			
Median (IQR)	0 (0–1)	0 (0–1·5)	0 (0–0)
Range	−3–11	−2–11	−3–5
P-value	0·006[a]		
Carryover effect			0·56[a]
Time difference (min:s)			
Median (IQR)	−00:09 (−00:25–00:13)	00:09 (−00:09–00:23·5)	−00:26 (−00:46 to −00:11)
Range	−06:45–00:58	−06:45–00:58	−01:53–00:16
P-value	0·008[a]		
Carryover effect			0·76[a]

IQR, interquartile range. [a]P-value calculated from Wilcoxon signed-rank test.

staff in addition to meeting the requirements outlined above. This computer-based method, which includes not only assessment but also scoring and presentation of QoL results, eliminates the need for a test administrator (interviewer), as usually needed for traditional paper and pencil formats, while providing immediate, 'real-time' feedback. Information from assessments can be displayed in graphic reports as visual aids that help guide discussions about treatment options and care planning. The availability of electronic versions of QoL instruments on various computer-based devices has the potential to reduce both the respondent burden and administrative time required to transfer the results of these PROs such as QoL scores to the clinician's desk, thus enhancing the feasibility and logistics of integrating real-time QoL assessment data for immediate use into routine clinical care to aid decision-making. A further benefit of electronic data capture is the ability to record time and date stamps, a feature particularly useful for diary data, in contrast to paper capture whereby

Table 4 Comparisons of applicability and practicality of paper and electronic versions of the Dermatology Life Quality Index

	All (n = 104)		Paper first (n = 57)		iPad® first (n = 47)	
Score[a]	Paper	iPad®	Paper	iPad	iPad	Paper
Ease of use, median (IQR)	10 (9–10)	10 (10–10)	10 (10–10)	10 (10–10)	10 (9–10)	10 (9–10)
Comfort, median (IQR)	10 (9–10)	10 (10–10)	10 (9–10)	10 (10–10)	10 (10–10)	10 (9–10)
Perceived time to complete iPad version						
Shorter than paper	57·7 (60)		70 (40)		43 (20)	
Same as paper	35·6 (37)		26 (15)		47 (22)	
Longer than paper	5·8 (6)		4 (2)		9 (4)	
Missing data	1·0 (1)		–		2 (1)	
Preference						
Paper	13·5 (14)		16 (9)		11 (5)	
iPad	76·0 (79)		75 (43)		77 (36)	
No preference	10·6 (11)		9 (5)		13 (6)	

Values are presented as % (n) except where otherwise stated. IQR, interquartile range. [a]10 = very easy or very comfortable; 1 = very difficult or very uncomfortable.

completion may occur at a different time to that recorded or intended. The computer-based measurement of QoL was well accepted by patients, who felt this method was a useful tool to inform the clinician about their problems.[28] Data are more complete on electronic questionnaires compared with paper questionnaires, data handling is greatly simplified, and the majority of patients prefer electronic completion.[29] Implementation of an electronic format of the DLQI could potentially streamline referral systems from primary care, allowing more appropriate allocation of appointments and resources. For example, the DLQI is integral to guidelines assessing the severity of psoriasis[30] and chronic hand eczema,[31] and referrals could potentially be triaged according to DLQI severity. In the research setting the availability of a web-based app would facilitate more efficient data collection in multicentre clinical trials and for longitudinal assessments of disease severity.

In response to increasing demand, a web-based app of the DLQI has been developed to encourage its further uptake in the current modernized clinical and research settings in many countries. Although computerized administration of QoL tools in other specialties has been shown to have numerous advantages over traditional paper-based tools,[32] this method of QoL assessment to present an overall disease severity idea has not yet been widely used in dermatology.

Level of education and literacy are important to consider when conducting PRO studies.[33] This study is representative of the general population, with the study participants' education ranging from secondary school (22·9%) to university level (37·6%). Previous experience with use of a tablet device did not affect results, with 17·3% of patients having never used one before and 46·2% stating that they were 'a little comfortable' or 'not comfortable' with using a tablet. Overall, 76% of patients preferred the iPad version, and found it easier to use and more comfortable than the paper version. Furthermore, 93% of patients perceived that the iPad was quicker to complete than the paper version or took the same amount of time, despite on average being slower by a median of 9 s ($P = 0·008$). Similar findings have been reported in many studies comparing electronic and paper PROs.[9,20,34] However, patients were aware of being timed when completing both versions, which could be a potential source of bias. Slower completion times could also be attributed to lack of familiarity of navigating on the iPad and occasional nonresponsiveness of the touchscreen. Investigators reported that various patients did not know how to 'touch' the screen appropriately and often searched for a 'next' button rather than scrolling down, despite instructions provided to the user on every occasion. This may be attributed to a simple design flaw in the app itself; navigation may be updated to become more intuitive. This study indicates that patients enjoy using the iPad more and the extra time spent had a negligible impact on patient experience. One concern expressed by a few patients included potential infection risk with shared iPads, though this may be less of an issue where personal electronic devices are used to monitor QoL changes over a period of time.

There are some limitations to the study. For example, a 30-min washout period may be considered too short and result in a carryover or 'training' effect, although there was no statistical evidence of this (Table 3). Theoretically, this may have occurred only when the iPad was administered first, as patients spent longer on average completing it, possibly giving them more time to remember the questions and answers. However, this effect was counteracted by the crossover study design, and patients were provided with reading material as a 'distraction'. Nevertheless, there is no consensus on the ideal time interval between PRO administrations when carrying out test–retest validation: intervals have ranged from 1 min to 7 years.[35] Other studies have also used 30 min as a washout period.[36] In order to reduce patient time and travel burden, as well as to ensure disease severity did not fluctuate between administrations, the shorter washout period of 30 min was used. Touchscreen surfaces are also prone to accidental touches, which may result in unintentional item responses subsequently

contributing to final score differences. The electronic version of the DLQI utilized in this study does not allow completion until all items are answered, which may impact validity if patients are coerced into answering questions they may have otherwise skipped on a paper format. This could have ethical implications from not giving patients the choice of not responding to a question if they do not wish to do so. In the DLQI, this issue is partly addressed by having a 'not relevant' option in eight of the 10 questions. The median score difference of '0' is unlikely to be clinically significant and strong correlation suggests that the two formats may be used interchangeably. Though the significant P-value of 0·006 for median total score difference is statistically significant, this is likely due to the large sample size.[37] Furthermore, the MCID for the DLQI is 4,[21] therefore the difference in scores is negligible in a clinical context. The limits of agreement from the Bland–Altman plots (−3·4–4·1) are also similarly reassuring. Differential item functioning was not assessed, as the DLQI total score is most relevant in clinical decision-making.[14]

Touchscreen devices offer many advantages, including portability and real-time assessment of QoL status.[38] Though this study did not involve full psychometric evaluation of the DLQI, there is evidence to suggest that where minimal modifications have been made, psychometric properties remain intact and need not be tested again.[10,20,39] While cognitive debriefing is suggested for equivalence studies of electronic PROs where only minor modifications are made,[10] this requirement was circumvented by using a higher threshold for testing equivalence (i.e. by comparing scores). It is hoped this will provide further reassurance for users who may have had concerns regarding the validity of scores from use of the DLQI in the previously nonvalidated electronic formats that have been used for many years. Formally testing such measures in this novel format provides confidence for end users who might otherwise have been reluctant to consider use of such formats because of concerns about validity or applicability. Thus, such studies may have wider and reassuring implications not only for the DLQI but also for other PROs within dermatology and across other medical specialties, encouraging early simultaneous validation of electronic and paper versions. Several challenges remain, including interface design decisions, data collection[40] and adapting electronic PROs to target populations, particularly in patients with physical disabilities or other impairments.[41] Nevertheless, this study has demonstrated that when DLQI migrates to an electronic format, scores are equivalent despite an overall slower completion time, which should become negligible with increased use and improvements to the app interface. This study provides evidence of equivalence for this app in particular (Psoriasis 360©), and future/other iterations of the electronic DLQI may not necessarily be equivalent. However, in most cases the changes to font size and layout are minor and thus repeated equivalence studies may be deemed unnecessary.[10]

The majority of patients preferred the electronic DLQI over the paper format, reflecting the findings of many similar studies.[30,42,43]

In conclusion, this study demonstrates equivalence in the measurement properties of paper and electronic formats, promoting confidence in the use of electronic format of the DLQI in both clinical and research settings, thereby paving the way for the digital era into current practices. The digital era in medicine will continue to be fuelled by a new generation of healthcare professionals who have been trained in this new platform. Patients and healthcare professionals are becoming more comfortable communicating and delivering their clinical expertise within a digital environment. In this context the electronic DLQI would be a valuable instrument in professionals' digital healthcare toolboxes, further facilitating its routine use.[44]

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